FH
FOURNITURES HOSPITALIERES

6, rue Nobel
Z.I. DE KERNÉVEZ
29000 QUIMPER
FRANCE
Tél : 02 98 55 68 95
Fax : 02 98 53 42 13

FHi industrie

NOV 17 2004

K042035 (pg 1 of 2)

510 (K) SUMMARY OF SAFETY AND EFFECTIVENESS
ALUMINA HEADS

SPONSOR IDENTIFICATION: Fournitures Hospitalières Industrie
6 Rue Nobel, Z.I. de Kernevez
29000 QUIMPER - FRANCE
Tel: (33) 2.98.55.68.95
Fax: (33) 2.98.53.42.13

ESTABLISHMENT REGISTRATION NUMBER: 3003898228

OFFICIAL CONTACT PERSON: Christine QUENDEZ
Regulatory Affairs Manager
E-mail: fhi.rd@wanadoo.fr

DATE PREPARED: JULY 10th, 2004

AFAQ ISO 9001

DEVICE TRADE NAME: ALUMINA HEADS

DEVICE COMMON NAME: Ceramic Femoral Head

CLASSIFICATION NAME: Hip joint metal/ceramic/polymer semi-constrained cemented or nonporous uncemented prosthesis

REGULATORY CLASS: Class II

G MED EN 46001

DEVICE PRODUCT CODE: 87 LZO

PANEL CODE: 21 CFR 888.3353

DEVICE DESCRIPTION:
Alumina heads are made of Biolox forte alumina (trademark of CERAMTEC) according to ASTM F 6474 standard.
Alumina heads have a 12/14 cone and are available in two diameters: 28mm and 32mm, with three offsets: -3.5; 0; +3.5.

SNITEM

INDICATIONS FOR USE:
Prosthetic replacement of the femoral head associated with a hip prosthesis having a taper compatible with the head taper, and with a prosthetic acetabulum having an inside diameter compatible with that of the head.

K042035 (p 2 of 2)

PREDICATE DEVICES:
Numerous alumina heads made of Biolox forte have been cleared for commercial distribution by the Food and Drug Administration (FDA). We have selected three predicate devices based upon intended uses, material used in device manufacturing and design features.

These predicate devices are:
- Apex Modular Alumina Femoral Head (K012918), Apex Surgical
- Biolox Alumina Ceramic Femoral Head (K981847 & K991162), Smith & Nephew
- Intraplant Ceramic Head Prosthesis (K990261), Plus Orthopedics

COMPARISON OF TECHNOLOGICAL CHARACTERISTICS:
Our alumina heads have the same intended use and substantial similar indications for use as the predicate devices. They are all made of the same material (Biolox forte), are available in similar diameters and lengths, with similar designs.
Performance tests were performed. Our proposed devices and the predicate devices were found to have results in compliance with the selected standard.

MATERIAL CHARACTERISTICS:
We have followed the FDA's guideline: "Guidance document for the preparation of premarket notifications for ceramic ball hip systems" dated January 10, 1995 to compare if our material characteristics were in conformity with the FDA requirements. Our alumina heads reach all the requirements set up in this guidance document.

PERFORMANCES:
To evaluate the safety and effectiveness of our Alumina heads, we have made two series of tests:
- Fatigue test and static compression test to rupture in the first series, and
- Pre-loading of femoral head on its neck at 2000 N and measurement of the head extraction force in the second series.

All the results were in compliance with the requirements set forth by the FDA.
Risk to health have been addressed through the specified materials, Processing controls, quality assurance and compliance to the Medical Device Good Manufacturing Practices Regulations.

CONCLUSION:
All these elements show the safety and effectiveness of our product. Our Alumina heads are substantially equivalents to the selected predicate device in terms of intended use, material, safety and effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 17 2004

Ms. Christine Quendez
Regulatory Affairs Manager
Fournitures Hospitalieres Industries
ZI de Kernevez
6 rue Nobel
29000 Quimper
France

Re: K042035
Trade/Device Name: Alumina heads
Regulation Number: 21 CFR 888.3353
Regulation Name: Hip joint metal/polymer/metal semi-constrained porous-coated uncemented prosthesis.
Regulatory Class: II
Product Code: LZO
Dated: November 1, 2004
Received: November 1, 2004

Dear Quendez:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

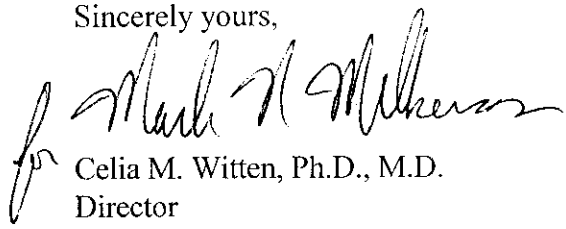
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,



Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K042035

Device Name: Alumina Heads

Indications for Use:

Prosthetic replacement of the femoral head associated with a hip prosthesis having a taper compatible with the head taper, and with a prosthetic acetabulum having an inside diameter compatible with that of the head.
The alumina head can only be used with polyethylene inserts.
This prothesis may be used for degenerative joint disease such as osteoarthritis and avascular necrosis, correction of functional deformity, rheumatoid arthritis, revision procedure where other devices or treatments have failed, congenital dislocation, femoral neck and trochanteric fractures, traumatic arthritis, fused hip, diastrophic variant, slipped capital epiphysis, non-union.

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K042035

Prescription Use ___X___ AND/OR Over the counter Use_____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Page __ of ___